Community views on factors affecting medicines resource allocation

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Community views on factors influencing medicines resource allocation: A cross sectional survey of 3080 adults in Australia

Abstract

Objectives: To determine Australian community views on factors that influence distribution of health spending in relation to medicines.

Methods: Cross-sectional web-based survey of 3080 adults aged 18 years or older. Participants were asked to rank, in order of importance, 12 criteria according to which medicines funding decisions might be made.

Results: 1213 (39.4%) of respondents considered disease severity to be the most important prioritisation criterion for funding a new medicine. This was followed by medicines treating a disease affecting children (13.2%), and medicines for cancer patients (9.1%). Medicines targeting a disease for which there is no alternative treatment available received highest priority from 8.6 % of respondents. The remaining 8 prioritisation criteria were each assigned a top ranking by respondents ranging from 6.6% to 1.7%. Medicines targeting a disease for which there is no alternative treatment available were ranked least important by 7.7% of respondents compared to 2.4%, 1.9% and 1.0% for medicines treating severe diseases, diseases affecting children and cancer, respectively. 'End-of-life treatments' and 'rare disease therapies' received the least number of highest priority rankings (2.0% and 1.7% respectively).

Conclusions:

These results provide useful information about public preferences for government spending on prescribed medicines. Understanding of public preferences on funding of new medicines will help the PBAC/government determine circumstances where greater emphasis on equity is required and help inform medicines funding policy that best meets the needs of the Australian population.

What is known about this topic? There is increased recognition of the importance of taking into account public preferences in the heath technology assessment (HTA) decision-making process.

What does this paper add? The Australian public view the severity of disease to be the most important funding prioritisation criterion for medicines, followed by medicines used to treat children or to treat cancer.

What are the implications for practitioners? The general public are capable of giving opinions on distributional preferences. This information can help inform medicines funding policy and ensure that it is consistent with the values of the Australian population.

Introduction

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for advising the government as to which medicines should be subsidised on the Pharmaceutical Benefits Scheme (PBS). In fulfilling this role, the PBAC is the steward of a large sum of public money: for the 12 months ending 30 June 2015, for example, total PBS spending amounted to $9.07 billion [1].

The PBAC makes its recommendations primarily on the basis of evidence of clinical effectiveness, safety and cost effectiveness derived from clinical trials and population-based observational studies. The PBAC also takes into account other factors, such as equity, in its consideration of what does, or does not, constitute "value for money". In this context, the term "equity" refers to access to PBS listed drugs in a manner that takes into account the distribution of benefits and potential harms based on factors such as prognosis, disease severity, age, distributional effect, context (eg. emergency or prevention), socioeconomic and geographical status and other issues not typically considered as part of quality of life measurements[2].

Previous analyses of PBAC recommendations demonstrated that the PBAC has been broadly consistent in its use of economic efficiency as a key criterion for decision making [3, 4]. The probability of a positive recommendation does increase with lower incremental cost effectiveness ratios but

there is no evidence of a fixed threshold for the value of a life year or a quality adjusted life year (QALY)[4]. Importantly, the PBAC has been found to actualise equity considerations by accepting a higher incremental cost effectiveness ratio (ICER) for medicines addressing a high unmet clinical need [5-7] and/or greater uncertainty in the available clinical evidence for rare diseases[8].

Further, the PBAC in its deliberation may consider the 'Rule of Rescue' (RoR). The consideration and application of RoR allows the PBAC to potentially reverse a decision not to recommend listing on the because of its consideration of comparative cost-effectiveness (and any other relevant factors). However, evidence (based on the published Public Summary Documents (PSDs) for past PBAC recommendations) indicates that the RoR has been applied infrequently by the PBAC and that there were few documented examples where application of the RoR has led to a positive PBAC recommendation[9]. PBAC consideration of the RoR requires the following four factors to be met: (1) no alternatives exist in Australia (2) the medical condition is severe, progressive and expected to lead to premature death (3) the medical condition applies to only a very small number of patients and (4) the proposed medicine provides a worthwhile clinical improvement sufficient to qualify as a rescue from the medical condition [2]. However, the relative influence/weight of the RoR factors is not quantitatively pre-defined. Importantly, the RoR as with other relevant factors supplements, rather than substitutes for evidence based consideration of cost-effectiveness [2].

The PBAC also provides advice on the inclusion of medicines on the Life Savings Drugs program (LSDP) [9]. The LSDP sits outside the PBS to provide an alternate funding arrangement for access to medicines that are not eligible for funding under the PBS due to unacceptable cost effectiveness. While those making submissions to the PBAC occasionally include population survey data on community preferences, assessments of equity are most commonly based on assumptions about community priorities. Given the central role that the general public has in funding publicly subsidised health technologies through taxes, and as beneficiaries of these technologies, it is increasingly recognised that this is inadequate, and that more information is needed about public preferences when making decisions about the funding of new medicines[10-12].

Around the world, government agencies responsible for the selection and reimbursement of prescribed medicines and other health technologies are increasingly concerned with how best to incorporate community preferences into their decision making[13, 14]. In Australia, the PBAC currently considers patients and the public views through consumer representation on the Committee, via an online consumer input process, as well as through consumer hearings convened by the PBAC for selected submissions. Recent examples of such hearings include those for lymphoma (brentuximab vedotin, bendamustine, idelalisib and obinutuzumab), which were considered at the March 2015 PBAC meeting [15], and for ovarian cancer and Morquio A syndrome (olarparib and elosulfase alfa respectively) which were considered at the March 2016 PBAC meeting [16].

Another important approach to eliciting consumer preferences, which supplements more direct forms of consumer engagement, is to conduct surveys of representative samples of the community. These have been used previously to support policy concerning the funding of cancer drugs in the UK[17], to assess the preferences for the funding of orphan drugs[18] and to understand public agreement with policies aimed to facilitate access to life-extending drugs used at the end of patients' lives[19]. To date, however, no representative community survey has explored how members of the Australian community rank various criteria according to their importance to funding decisions for prescribed medicines. We therefore conducted an on-line survey of 3080 Australians aged 18 years or older in order to measure community preferences for the distribution of the benefits and costs of PBS listed drugs.

Methods

We undertook a cross sectional web based survey of 3080 adult Australians aged 18 years or older. This paper focuses on the findings from the ranking exercise conducted as part of the present study.

SSI, a market research company with a large online panel (~ 409,000 registered members) was used to recruit survey participants. Recruitment was controlled by gender, age and geographical area

(state of residence) in order to ensure that the sample was representative of the general adult Australian population. Participants were compensated for their time and received 'reward points' averaging $1.40 from the panel provider. Selection of the 12 prioritisation criteria was informed by both the published literature and criteria currently used by the PBAC when assessing new medicines for public subsidy. [5,6,7,8, 9,10] The 12 prioritisation criteria, were: (1) severity of disease (2) availability of alternative medicine (3) significant innovation (4) carer burden (5) disadvantaged populations (6) children (7) end-of-life treatments (8) cancer treatments (9) rare disease therapies (10) cost to the PBS and savings to patient (11) medicines that help patients return to work (12) Life-style related diseases and individual responsibility.

The survey asked respondents which criteria they believed were the most important in healthcare spending and resource allocation. Respondents were asked to rank the 12 prioritisation criteria from one to 12, with one being the most important criterion. The survey was pilot tested with 111 participants in August 2015. An additional question regarding the state of residence was added after pilot testing. The full survey was administered during October 2015 and closed when our target of 3000 complete responses was achieved. Socio-demographic data were collected to test associations between respondents' views on the prioritisation criteria and demographic characteristics.

Ethics approval

This study was approved by Human Ethics Research Committee at Sydney University (protocol number: 2014/906).

Statistical analysis

Descriptive statistics were used to summarize demographic variables. Empirical studies have found that willingness to pay and funding preferences are influenced by respondents' personal circumstances such as age, income, health status, household composition[17, 20]. Multinomial logistic regression modelling was used to assess whether gender, age, marital status, education , health status, cancer history, country of birth, private health insurance, employment status, household

income, and dependent children were associated with the top ranking of the 12 prioritisation criteria. The model included all explanatory variables listed.

Results

A total of 3080 adult members of the general public in Australia completed the on-line survey. The 3080 respondents broadly reflected the Australian population in terms of age, gender and geographical area (**Table 1**). 39.4% of respondents considered disease severity to be the most important prioritisation criterion (**Table 2**). This was followed by medicines for diseases affecting children (13.2%). Cancer medicines came third and were ranked most important by 9.1% of respondents, while medicines targeting a disease for which there is no alternative treatment available received highest priority from 8.6 % of respondents. The remaining 8 prioritisation criteria were each assigned a top ranking by respondents ranging from 6.6% to 1.7%.

The four prioritisation criteria that were assigned the highest priority, also received the largest number of top 3 rankings: disease severity (n= 1966, 21.3%), medicines for children (n= 1260, 13.6%), cancer medicines (n= 1112, 12.0%), and medicines targeting a disease for which no other medicine is available (n= 957, 10.4%).

Medicines targeting a disease for which there is no alternative treatment available were ranked least important (i.e. with a respondent's assigned rank order of 12) by 7.7% of respondents compared to 2.4%, 1.9% and 1.0% for medicines treating severe/life threatening diseases, treating a disease affecting children and medicines for cancer patients, respectively.

'End-of-life treatments' and 'rare disease therapies' received the least number of highest priority rankings (2.0% and 1.7% respectively).

Relationship between respondent characteristics and prioritisation preferences

Country of birth (p= 0.04), employment status (p= 0.04) and having dependent children (p= 0.0001) were associated with funding preferences (see Supplementary file). Respondents who were born overseas were significantly more likely to assign a top priority to medicines that help patients return to work (OR= 1.57, 95% CI= 1.06 to 2.32, p= 0.02), and to medicines targeting life style unrelated diseases (OR= 1.57, 95% CI= 1.01 to 2.42, p= 0.04) than to prioritise disease severity, compared to those born in Australia. Respondents with dependent children were significantly more likely to assign a top ranking to medicines targeting diseases affecting children (OR= 2.04, 95% CI= 1.52 to 2.78, p<0.0001), and to cancer medicines (OR= 1.45, 95% CI= 1.01 to 2.04, p= 0.04). Respondents who are in part time employment were significantly less likely to assign a top finding priority to medicines targeting rare diseases than those working full time (OR= 0.19, 95% CI= 0.05 to 0.66, p= 0.01). Compared to respondents who were in full time employment, respondents who were neither in employment nor unemployed (i.e. 'other' category, for example those who were looking after a home or studying full time) were significantly more likely to assign a top ranking to medicines targeting diseases that affect patients who are not financially well off (OR= 1.72, 95% CI= 1.02 to 2.87, p= 0.04). Further, these respondents were significantly less likely to allocate the highest funding priority to medicines targeting life style unrelated diseases (OR= 0.15, 95% CI= 0.03 to 0.63, p= 0.01) compared with those in full time employment.

There was also some evidence that health status (P= 0.06) and private health insurance (P= 0.06) were associated with funding preferences. Compared with respondents rating themselves as in very good health, respondents who rated themselves as in good, average, or poor/very poor health were significantly more likely to assign a top ranking to medicines targeting diseases that affect patients who are not financially well off (OR= 1.90, 95% CI= 1.13 to 3.20, p= 0.02; OR= 2.33, 95% CI= 1.35 to 4.01, p= 0.002; OR= 2.40, 95% CI= 1.20 to 4.79, p= 0.01 respectively), and to medicines that cost the government more and thereby save patients more in out-of-pocket costs (OR= 2.25, 95% CI= 1.19 to

4.26, p= 0.01; OR= 2.18, 95% CI= 1.11 to 4.28, p= 0.02; OR= 3.12, 95% CI= 1.39 to 7.02, p= 0.006 respectively). Respondents who do not have private health insurance were significantly more likely to allocate the highest funding priority to medicines that cost the government more, thereby saving patients more in out-of-pocket costs compared to those with private health insurance (OR= 1.58, 95% CI= 1.07 to 2.31, p= 0.02). ,

Discussion

The results of our study give a clear picture of public preferences regarding resource allocation for medicines. The targeting of severe or life threatening diseases is clearly and by far the most important prioritisation criterion , followed by medicines targeting diseases affecting children, cancer medicines and medicines targeting diseases for which no treatment alternative is available. Whilst the first three top ranking prioritisation criteria were assigned a least important ranking by a small proportion of respondents (1 to 2.4%). Medicines targeting a disease for which no alternative treatment exists were ranked most and least important by a similar proportion of respondents (8.6% and 7.7%, respectively). One possible explanation for this variation is that societal opinion on the use of this as a prioritisation criterion for new medicines funding may be divided and 'polarised'.

Further, findings from this study resonate with previous studies[11, 17, 19, 21, 22], which have shown that members of the general public give higher priority to medicines used for the treatment of severe illness and for those with no available alternatives. The finding of support for prioritising anti-cancer medicines is also generally consistent with existing evidence[23, 24], and could explain the current focus both in Australia and internationally on achieving timely access to such treatments[25]. However, as cancer medicines are the only disease specific medicines explored in this study, this finding should be interpreted with caution. We found no compelling evidence for prioritising end-of-life treatments. This is consistent with a study by Linley et al[17], which examined the views of the UK general public about the current and proposed medicines prioritisation criteria used by the UK National Institute of Health and Care Excellence (NICE) and government.

Our study suggests that rare disease therapies *per se* are not a strong driver for public funding preferences. Although this is consistent with other research[17, 18], it is nonetheless a somewhat surprising finding given that rarity of disease is one of the four criteria that form the basis of the 'rule of rescue' (RoR) PBAC claim[2]. A RoR applies in exceptional circumstances for drugs that provide a worthwhile benefit for a severe and rare condition for which there is no alternative treatment[2, 9, 26]. The results of our study suggest that the use of rarity of the disease as an inclusion criterion for LSDP or as a basis for a RoR claim does not appear to be supported by the Australian public. One possible interpretation of this result is that rarity is not a shared prioritisation criterion between the general public and the PBAC. Given that rarity of the disease is linked to the total number of eligible patients and cost for funding a medicine, it is, and may need to remain, an important prioritisation criterion from the PBAC/government perspective, especially for high cost medicines.

An important strength of our study is that it included a large, broadly representative sample of 3080 adult Australians. However, due to the design of our study, non-completion rates and details of non-responders were unavailable for analysis or assessment for potential non-responder bias. Another potential limitation relates to framing effects. It has been found that the choice of wording in surveys is very important[27]. The results for the prioritisation criterion relating to life-style unrelated diseases appear to be somewhat surprising, with the largest proportion of respondents ranking this criterion last. It is possible that respondents' preferences may have been confounded by the labelling choice used in the survey. Despite these limitations, our study has important implications for health policy development with respect to the funding of new medicines in Australia.

Further, our research shows that respondents' funding preferences for access to new medicines are influenced by their personal characteristics and circumstances. Therefore, if the general public's views and preferences are to be included in the PBAC decision making process, a representative sample is required.

In summary, the findings of this study provide assurance that the Australian public support some of the currently used prioritisation criteria. However, quantification of criteria weights and equity issues relative to other factors will require further research in order to provide guidance to the PBAC on the cardinality of equity preferences and quantification of ICER increase to account for the specific equity issues/criteria identified.

Conclusions

The reimbursement of prescribed medicines should reflect both evidence of safety and effectiveness, and social values[28]. As such, it is important to understand societal views and preferences for the distribution of healthcare spending. Results of this study provide useful information on public preferences related to the equity aspects of government spending on prescribed medicines in Australia. Understanding of public preferences on funding of new medicines could help the PBAC/government determine circumstances in which greater emphasis on equity is required, and how equity might be defined and achieved in a manner that is congruent with the values of the Australian population. To ensure that public preferences are reflected in the PBAC's assessments and recommendations, there is a need for further research to determine the best way to incorporate these preferences into PBAC decision making processes. This will, in turn, improve alignment between government and societal preferences for funding of new medicines[29, 30].

236 **Table 1: Characteristics of respondents (N=3080)**

Characteristics	N	%	Australia[2] %
Gender			
Male	1502	48.8	48.9
Female	1578	51.2	51.1
Age (years)			
18-24	374	12.1	12.2
25-34	542	17.6	18.0
35-44	596	19.4	18.5
45-54	553	18.0	17.9
55-64	481	15.6	15.2
65+	534	17.3	18.2
Marital status			
Married/de facto	1832	59.5	
Separated/divorced/widowed	406	13.2	
Never married	842	27.3	
Education			
Never attended school/ primary/ some high school/ preferred not to answer	444	14.4	
Completed high school	627	20.4	
University, TAFE etc.	2009	65.2	
Cancer history			
Cancer history with death	1175	38.1	
Cancer history with no death/death unknown	489	15.9	
No cancer history	1376	44.7	
Prefer not to answer	40	1.3	
General health			
Very good	544	17.7	
Good	1481	48.1	
Average	842	27.3	
Poor/ very poor	213	6.9	
Country of birth			
Australia	2285	74.2	
Overseas	795	25.8	
Private health insurance			
Yes	1814	59	
No	1266	41	
Employment status			
Working full time	1082	35.1	
Working part time	622	20.2	
Currently not working, but looking for work	376	12.2	
Retired	669	21.7	
Other	331	10.7	
Household annual income			
$0 to 20,000	249	8.1	
$20,001- 40,000	610	19.8	

$40,001 to 80,000	863	28.0	
$80,001 and over	1008	32.7	
Prefer not to answer	350	11.4	
Personal annual income			
$0 to 20,000	754	24.5	
$20,001- 40,000	711	23.1	
$40,001 to 80,000	792	25.7	
$80,001 to 180,000	422	13.7	
$180,001 and over	47	1.5	
Prefer not to answer	354	11.5	
Household composition			
With financially dependent children	927	30.1	
Without financially dependent children	2153	69.9	
State			
Australian Capital Territory	47	1.5	1.7
New South Wales	985	32.0	32.2
Northern Territory	10	0.3	0.9
Queensland	587	19.1	19.9
South Australia	236	7.7	7.6
Tasmania	70	2.3	2.3
Victoria	745	24.2	25.1
Western Australia	289	9.4	10.4
Unknown[1]	111	3.6	-

[1] The pilot survey did not include this demographic question (n= 111)

[2] Australia demographics (gender, age and state of residence) are for persons aged 18 years and over, sourced from the TableBuilder available from the Australian Bureau of Statistics based on the 2011 Census data. (http://www.abs.gov.au/websitedbs/censushome.nsf/home/tablebuilder?opendocument&navpos=240).

Abbreviation: TAFE= Technical and Further Education

242 **Table 2: Number of times a prioritisation criterion was assigned the top priority, lowest priority**
243 **(i.e. with a ranking order of 1 and 12 respectively), and top 3 rankings by respondents**

Prioritisation criteria	Rank 1 (most important) n (%) N= 3080	Rank 12 (least important) n (%) N=3080	Top 3 rankings n (%) N= 9240
Severity of disease Preference for funding should be given to new medicines that treat severe or life threatening conditions	1213 (39.4)	73 (2.4)	1966 (21.3)
Children Preference for funding should be given to new medicines targeting diseases that typically affect children	405 (13.1)	57 (1.9)	1260 (13.6)
Cancer treatments Preference for funding should be given to new medicines targeting cancer patients	280 (9.1)	30 (1.0)	1112 (12.0)
Availability of alternative treatment options Preference for funding should be given to new medicines that target diseases for which no other treatments are available	266 (8.6)	236 (7.7)	957 (10.4)
Disadvantaged populations Preference for funding should be given to new medicines targeting diseases that typically affect disadvantaged patients e.g. low income families	204 (6.6)	161 (5.2)	760 (8.2)
Cost to the PBS and savings to patient Preference for funding should be given to new medicines that cost the government more and thereby save patients more in out-of-pocket costs	139 (4.5)	288 (9.4)	474 (5.1)
Medicines that help patients return to work Preference for funding should be given to new medicines that help patients return to work	133 (4.3)	200 (6.5)	508 (5.5)
Carer burden Preference for funding should be given to new medicines targeting diseases that, if untreated, cause patients to be reliant on carers	110 (3.6)	146 (4.7)	594 (6.4)
Life style related diseases and individual responsibility Preference for funding should be given to new medicines targeting diseases that are not considered to be a life-style related disease i.e. diseases that could not be avoided through individual life style changes	109 (3.5)	1041 (33.8)	296 (3.2)
Significant innovation Preference for funding should be given to new medicines that work in a new and different way to existing treatments	107 (3.5)	221 (7.2)	569 (6.2)
End-of-life treatments Preference for funding should be given to new medicines that prolong life –even for a few months- at the end of life i.e. for patients with a life expectancy of less than 2 years	63 (2.0)	476 (15.5)	363 (3.9)
Rare diseases Preference for funding should be given to new medicines targeting rare diseases i.e. diseases affecting less than 2000 patients in Australia	51 (1.7)	151 (4.9)	381 (4.1)

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